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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,901	08/07/2001	Kanji Takada	P21010	2415
7055	7590	04/21/2005	EXAMINER	
GREENBLUM & BERNSTEIN, P.L.C.			GHALI, ISIS A D	
1950 ROLAND CLARKE PLACE			ART UNIT	
RESTON, VA 20191			PAPER NUMBER	

1615

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/831,901

Applicant(s)

TAKADA, KANJI

Examiner

Isis Ghali

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-18 and 20-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-18, 20-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The receipt is acknowledged of applicant's request for extension of time and amendment, both filed 01/10/2005.

Claims 9 and 19 have been canceled. Claims 1-8, 10-18 and 20-25 are pending and included in the prosecution.

**The following new ground of rejection is necessitated by applicant's amendment:**

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to claim 8 has introduced new matter that has not been disclosed in the specification as originally filed, and that is the recitation of the protecting film layer composed of one water-insoluble polymer and a wax. The

specification disclosed at page 11, first full paragraph that the protecting film layer is made of water-insoluble polymer or wax.

**The following rejection was discussed in details in the previous office action, and maintained for reasons of record:**

3. Claims 1-8, 10-18, and 20-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

***Response to Arguments***

Applicant's arguments filed 01/10/2005 have been fully considered but they are not persuasive. Applicant traverses the enablement rejection by arguing that the rejection does not clearly state what the Examiner considers to be non-enabled. Applicant submits that examples in the specification provide examples of both oral administration as well as surgery being utilized to place formulations in the duodenum through a cut in the stomach near the pylorus and the location of the formulation being subsequently determined. Applicant submits that Applicant's specification discloses Applicant's invention so that one having ordinary skill in the art can practice the invention without undue experimentation following the guidance provided in Applicant's specification. Thus, Applicant's specification describes that the adhesion-site controlling layer dissolves at a suitable site in the GI-tract and that it is made of PH dependent enteric polymer. Applicant notes that the adhesion site-controlling layer used in the present invention is composed of an enteric polymer as described in the specification. The adhesion site-controlling layer does not have a function of being attached to the mucous

membrane. A drug-carrying layer for containing a drug and an adhesive is attached next to the adhesion site-controlling layer. This drug-carrying layer has a function of being attached to the mucous membrane. It is also well known to those having ordinary skill in the pharmaceutical art that enteric polymers do not dissolve in water or acidic aqueous solutions. Applicant submits that sufficient guidance has been presented in the application so that one having ordinary skill in the art can practice Applicant's invention without undue experimentation. In particular, Applicant's have provided a thorough disclosure of formulations according to Applicant's invention, and one having ordinary skill in the art can practice Applicant's disclosed and claimed invention without undue experimentation.

In response to these argument, the examiner is pointing out to the breadth of claim 1 that is directed to oral formulation that can reads on tablet, while the specification and the examples are directed to patch consisting of three film layers that are laminated, page 3, first full paragraph; page 4, first full paragraph; page 12, first full paragraph, page 14, first full paragraph; examples 1-4. Therefore, the specification has enabled patch consisting of the three claimed layers, and has not enabled any other oral formulation. The specification provides guidance to oral patch film consisting of the three claimed layers. The state of the art recognized two-layered patch, one film layer containing the drug, and the adhesive layer made of enteric polymer, as disclosed by US 4,765,983. The sate of the art has not recognized the patch of three laminated layers as claimed. One having ordinary skill in the art will turn into trial and error to practice the present invention in absence of enough guidance from the specification and

the prior art in terms of oral formulations other than the patch that stick to the intestinal mucosa and consisting of the three laminated layers as claimed.

### ***Conclusion***

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali  
Examiner  
Art Unit 1615

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**THURMAN K. PAGE**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**